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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,981	01/23/2001	Ejvind Jensen	4343.214-US	2751

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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)	
09/767,981	JENSEN ET AL.	
Examiner	Art Unit	
David S Romeo	1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *21 October 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *15-23*.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

David S Romeo
Primary Examiner
Art Unit: 1647

Continuation Sheet (PTOL-303) **Application No.**
09/767,981

Continuation of 5. does NOT place the application in condition for allowance because: Claims 15-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for GLP-1, does not reasonably provide enablement for GLP-1 compounds. Applicant argues that the specification teaches how to prepare a thixotropic gel. Applicant's arguments have been fully considered but they are not persuasive because this argument is not germane to the present rejection. With respect to GLP-1 compounds Applicant argues that the present application discloses GLP-1 compounds that can be used to formulate the compositions of the invention, and that analogs and derivatives of GLP-1 were known in the prior art. Therefore, the present application teaches the materials and conditions necessary to produce the claimed compositions. The scope of the term "GLP-1 compound" does not bear a reasonable correlation to the scope of enablement provided by the specification because the specification only reasonably enables compounds comprising fragments of the amino acid sequence of GLP-1 wherein said fragments bind the GLP-1 receptor, whereas the scope of the term "GLP-1 compound" encompasses any and all compounds having GLP-1 like activity.

Claims 15-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant argues that the present application discloses GLP-1 compounds that can be used to formulate the compositions of the invention, and that analogs and derivatives of GLP-1 were known and understood by the prior art, such as U.S. Patent Nos. 5,545,618, 5188,666, and 5,120,712. Applicant's arguments have been fully considered but they are not persuasive. U.S. Patent Nos. 5,545,618 and 5188,666 are not disclosed in the present disclosure. The claimed GLP-1 analogs and derivatives in U.S. Patent No. 5,120,712 all comprise a specific amino acid sequence. In contrast, the present claims do not require any specific amino acid sequence.

Claims 15-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, over the recitation of the term "GLP-1 compound." Applicant argues that the present application discloses GLP-1 compounds that can be used to formulate the compositions of the invention, and that analogs and derivatives of GLP-1 were known and understood by the prior art, such as U.S. Patent Nos. 5,545,618, 5188,666, and 5,120,712. Applicant's arguments have been fully considered but they are not persuasive. U.S. Patent Nos. 5,545,618 and 5188,666 are not disclosed in the present disclosure. The claimed GLP-1 analogs and derivatives in U.S. Patent No. 5,120,712 all comprise a specific amino acid sequence. In contrast, the present claims do not require any specific amino acid sequence. The metes and bounds are not clearly set forth.

Claims 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Danley (4, cited by Applicants) in view of Avis (u10), and further in view of Galloway (a13), Schott (y7), and Ballard (x7). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. The phenol and zinc elements of the presently claimed invention are all found in Danley. Danley teaches that a prolonged delivery formulation being an aqueous suspension of insulinotropin precipitates or aggregates can be formed by using precipitants for example, phenolic compounds or basic polypeptides or metal ions or salts, and/or by using high shear and that more than one precipitant can be used at one time (page 18, lines 43-45). The examiner relies upon Avis for teaching that phenol is an antimicrobial agent. The examiner does not rely upon Galloway to supply zinc. Although Ballard may disclose other methods besides thixotropy for achieving prolonged action, Ballard discloses the advantages of thixotropy (page 1610, right column, full paragraph 3), which would motivate one of ordinary skill in the art to select thixotropy. The precipitation of GLP-1 by zinc is recognized by both Danley and Galloway. Danley recognizes that this is useful for the creation of a prolonged delivery formulation. Furthermore, Schott teaches that thixotropy is particularly useful in the formulation of pharmaceutical suspensions and emulsions; thixotropy can be used to solve the dilemma involving low viscosity and rapid settling of solid particles in suspensions and rapid creaming of emulsions; thixotropy prevents sedimentation and claying of suspended particles; Schott also teaches thixotropic agents (page 318, column 1, full paragraph 1). The precipitation of GLP-1 zinc would motivate one of ordinary skill in the art to select thixotropy because thixotropy prevents sedimentation and claying of suspended particles. Thus, the teaching of the precipitation of GLP-1 with zinc is not a teaching away from the creation of a prolonged delivery formulation or the creation of a gel comprising GLP-1 and zinc.